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DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE

Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

April 17, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jeremy M. Jones
Chief Executive Officer/Chairman
Apria Healthcare Group, Inc.
3550 Hyland Avenue
Costa Mesa, California 92626

PURGED

Ref. # - DEN-97-16

Dear Mr. Jones:

During an inspection of your firm, Apria Healthcare, Inc., 4401 McLeod Road, NE, Suite C, Albuquerque, New Mexico, on February 3 through 10, 1997, Investigator Cynthia Jim determined that your firm transfills liquid and compressed medical oxygen. Medical oxygen is a drug as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). The above stated inspection revealed that your product, Oxygen, U.S.P., is adulterated in that the controls used for the manufacturing, processing, packing, or holding of this product are not in conformance with current good manufacturing practice regulations under Title 21, Code of Federal Regulations (21 CFR), parts 210 and 211. Deviations noted during the inspection include, but are not limited to the following:

1. [21 CFR 211.25] A failure to provide sufficient Good Manufacturing Practice (GMP) regulation training to personnel engaged in the manufacture, processing, packing, or holding of compressed medical gas products to enable personnel to perform the assigned functions. For example, a review of the following records revealed personnel were not consistently recording the entries indicated:
   A. Oxygen Pumping Logs - the date, oxygen purity reading, cylinder temperature reading, cylinder pressure reading, liquid batch number, fill pressure reading, completion of filling and after filling procedures, serial number of cylinder tested, size and quantity of cylinders filled, time filled, number of units rejected, number of labels used, pumper's signature, and supervisory signature.

B. Daily Route Sheet/Manifest records - the date, location, unit number, driver identification, liquid oxygen batch number, prefill checks, calibration of oxygen analyzer, driver's signature, auditing official's signature, et al.
C. Oxygen Label Control Logs - the number of labels used, type of label used, number of labels on hand at end of day, name of personnel performing the function, and auditing personnel's signature.
D. Vendor Tested Product Verification Logs - when bulk liquid oxygen deliveries were made, vendor invoice/delivery ticket number, proper lot number, vehicle number or license plate number, oxygen purity percent, testing employee's initials, witnessing employee's initials, and reviewer's initials.
E. Analyzer Calibration Logs - the analyzer's serial number, daily calibration, lot number of bulk oxygen purity tested, technician's initials, and reviewing supervisor's initials.

2. [21 CFR 211.192] A failure to review and approve all drug product production and control records, including those for labeling, to determine compliance with all established, approved written procedures before a batch was released or distributed. For example,
A. The Analyzer Calibration Log indicated that supervisory personnel failed to completely audit documents for the following months: 9/96, 11/96, and 1/97.
B. The Oxygen Label Control Logs did not indicate any review.
C. Numerous Route Sheet/Manifest records, which lacked vital information, failed to have supervisory review/initials.
D. The Vendor Tested Product Verification Log indicated supervisory review/initials on a line with no entries between the dates 8/1/96 and 8/12/96, and lacked supervisory review/initials on the following dates: 9/30/96, 11/21/96, 11/27/96, and 11/30/96.
E. The Oxygen Pumping Logs reviewed the following Logs lacking supervisory review:
1. batch records in 09/96
2. batch records in 11/96
3. batch records in 12/96

3. [21 CFR 211.67(b)] A failure to establish written procedures for cleaning and maintaining the Model in that, (A) a legible copy of the manufacturer's user manual was not made available to employees, and (B) operating procedures posted in the filling room lacked instructions for complete calibration and maintenance according to the manufacturer's guidelines.

4. [21 CFR 211.67(a)] A failure to clean, maintain, and sanitize the Model which was placed in service about 1992 or 1993, at appropriate intervals and in accordance with established specifications and procedures. For example:
A. The filter was not checked on a weekly basis or changed.
B. The analyzer zero was not checked after the analyzer underwent a temperature change of or more.
C. The drying tube was not checked for every calibration. performed.

5. [21 CFR 211.160(d)(4)] A failure to calibrate the . Model used in testing bulk oxygen, and Model used in testing high pressure cylinders and oxygen concentrator units. For example,
   A. calibration was not performed according to procedures, in that,
      1. the Analyzer Calibration log did not indicate which bulk oxygen lot was tested,
      2. the Oxygen Delivery Log indicated a delivery of bulk oxygen on 7/10/96, but the Analyzer Calibration Log did not document calibration was performed, and
      3. Oxygen lot # 3412006C with a Certificate of Analysis dated 12/6/96 was delivered to the firm, but the Analyzer Calibration Log did not document that calibration was performed.
   B. calibration was not documented on Daily Route Sheet/Manifest records.

6. [21 CFR 211.165(a)] A failure to test at least one cylinder of each batch of high pressure cylinders for identity and strength prior to release for distribution.

7. [21 CFR 211.165(e)] A failure to assure the accuracy and sensitivity of the test methods used in the testing and release of batches of high pressure cylinders in that the used in batch testing had an accuracy of % according to the analyzer's manual, but the requirement for purity was . %.

8. [21 CFR 211.192] A failure to review and approve production and control records prior to release and distribution of drug products. For example,
   A. The Analyzer Calibration Log indicated that the analyzer was calibrated on the following Saturdays and Sundays even though calibration never took place on weekends. For example, the log indicated calibration took place on the following weekend dates: 9/21/96, 10/6/96, 10/12/96, 10/27/96, 11/2/96, 11/2/96, 11/9/96, 11/30/96, 12/21/96, 12/28/96, and 1/25/97.
   B. No documentation was found to indicate that filling and post filling procedures were performed on cylinder lot # 23596, rack #3.
   C. The . Batch numbers recorded on Route Sheet/Manifest records for July through December 1996 did not match the Batch numbers on the Oxygen Delivery Logs.
   D. The Route Sheet/Manifest records for 12/96 failed to include documentation for one or more of the following: stop #, Arrive/Depart, #, vessel pre-fill checks, analyzer calibration, Batch #, Hazardous Material Manifest, driver signature, and/or audited by initials.

9. [21 CFR 211.130] A failure to control labels and labeling. For example,
   A. Records were not maintained for the receipt, examination, and acceptance or rejection of labels.
   B. Access to labels stored in an unlocked filing cabinet was not controlled.
   C. Quantities of labels issued, used, and returned were not always recorded.
   D. Finished product labels were not always verified as correct.

10. [21 CFR 211.82(b)] A failure to store drug product containers to prevent mixups. For example, empty, filled, tested, and untested cylinders were observed commingled in the filling room.

11. Labels did not always contain the following information: [21 CFR 201.100] A statement that Oxygen, USP was or was not produced by air-liquefaction, [21 CFR 201.100(b)(1)] the statement "Caution: Federal law prohibits dispensing without prescription," and [21 CFR 201.1] the name and place of business of the manufacturer, packer, or distributor.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. As Chief Executive Officer of this company, it is your responsibility to assure adherence with all requirements of the Good Manufacturing Regulations.

At the conclusion of the inspection, Investigator Cynthia Jim issued a written report of observations (FDA 483) to Mr. William E. Carpenter, Albuquerque Branch Manager. A copy of this report is enclosed for your reference.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, including seizure or injunction, without further notice. Federal agencies are advised of the issuance of all warning letters so that they may take this information into account when considering the award of contracts.

We acknowledge receipt of the response to the Form FDA 483 dated February 19, 1997 from Ruth Ann Ellison, Corporate Director of TQM/Accreditation and Licensing. The response appears to adequately address our concerns. Your corrective actions will be evaluated during our next scheduled inspection.

Please advise this office, in writing, within fifteen (15) working days after receipt of this letter, of the specific actions you have taken to correct the violations. You may refer to Ms. Ellison's previous letter. Your response should include: (1) each step that has or will be taken to completely correct the current violations and prevent the recurrence of similar violations; (2) the time when correction will be completed; (3) any reason why the corrective action is not completed within the response time; and (4) any documentation necessary to indicate correction has been achieved. Your response should be directed to Mr. Russell W. Gripp, Compliance Officer, at the above address.

Sincerely,

Gary C. Dean
District Director

Enclosure

cc: Mr. William E. Carpenter
Branch Manager
4401 McLeod Road, NE, Ste. C
Albuquerque, New Mexico 87109

cc: Ms. Ruth Ann Ellison
Corporate Director, TQM/Accreditation and Licensing
3560 Hyland Avenue
Costa Mesa, California 92626